

### **REMARKS**

Entry of this Amendment is proper under 37 C.F.R. § 1.116 because the Amendment places the application in condition for allowance for the reasons discussed herein; and does not raise any new issues requiring further search and/or consideration as the amendments amplify issues previously discussed throughout prosecution. Entry of the Amendment is thus respectfully requested.

Claims 1, 4, 5, 10-12 and 18-19 are amended herein. Claims 1 and 12 are amended herein to recite "buffy coat" as the starting material. Claim 10 is amended herein to recite "cleaning/sanitizing said centrifuge, retention vessel and mixing device, as well as the filter means that accomplish said filtration in step (a)". Claims 4, 5 and 11 are amended to bring the dependent claims into line with independent claims 1, as amended herein. Claims 18-19 are amended to address issues of antecedent basis.

Basis for these amendments may be found throughout the specification and claims as-filed, at Example 2 (pages 15-16), especially at page 15, lines 2-9, as well as page 5, lines 13-27, page 7, line 9 to page 8, line 4 (discussing filtration parameters). Claim 2 has been deleted as redundant in light of the amendment to claim 1. No prohibited new matter is presented by way of the present Amendment. Applicants reserve the right to file continuation or divisional applications directed to any subject matter deleted by way of the present Amendment.

### **Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 1-12 and 15-21 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite. Specifically, the Office Action states that there is an unrecited critical step of settling the blood prior to the filtration step in claims 1 and 12.

Without ceding to the Examiner's rejection and in the interest of expediting prosecution, Applicant has amended independent claims 1 and 12 to recite "buffy coat" as the starting material and removed blood as a starting material.

Claim 10 stands rejected for purportedly failing to indicate where the recited steps occur in relation to in claim 1. The Office Action states that the added steps refer to "a system at site", but that it is not clear what the components of the system may be.

Applicant submits that the subject matter of claim 10 does not recite an additional step to claim 1. Rather, the fact that the process is automatically operated and adapted for CIP and SIP is a feature of the process as a whole. To clarify this point, and to further clarify which system components are contemplated, claim 10 is amended herein to replace "cleaning a system at site" or "sanitizing a system at site" with the recitation of cleaning/sanitizing the centrifuge, retention vessel and mixing device, as well as the filter means that accomplish said filtration in step (a) of claim 1.

Claim 12 stands rejected for purportedly failing to recite a critical disclosed component of the apparatus (the static mixer) and for purportedly failing to recite two embodiments recited in the preamble. Claim 12 is amended herein to recite the static mixer in element (ii), as well as to clarify what Applicant intends as the claimed invention. Specifically, as the preamble of claim 12 now recites purification and concentration of leukocytes, Applicant submits the preamble and body of the claim are commensurate in scope.

Claim 18 stands rejected for the recitation of the term "apparatus" as it purportedly lacks antecedent basis in claim 11. Claims 18 and 19 are amended herein to depend upon claim 12.

In light of these remarks and amendments to the claims, Applicants request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

**Rejections under 35 U.S.C. § 112, First Paragraph**

Claims 1, 3-12 and 15-19 also stand rejected as purportedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claim 1, the Office Action states that the recitation of obtaining leukocytes from blood is not enabled. Without ceding to the Examiner's rejection and in the interest of expediting prosecution, Applicants has amended claim 1 to remove the recitation of deriving leukocytes from blood. Rather, the claims recited the derivation of leukocytes from the buffy coat fraction.

Claims 12 and 15-19 stand rejected for purportedly failing to disclose and apparatus which achieves lysis in a retention vessel, without having a static mixer provided in line, prior to the vessel. Applicant notes that the apparatus of claims 12 and 15-19 is used for continuous purification and concentration of leukocytes from the starting material, the buffy coat fraction. With regard to element (ii) of independent claim 12, mixing occurs in the static mixer, while in element (iii), lysis occurs in the retention vessel. Regarding filtration, plasma is usually separated from blood by centrifugation. The plasma is separated from a buffy coat fraction via filtration, so that a filtered buffy coat fraction is obtained. To clarify this point, independent claim 12 is amended herein to recite the static mixer means (which mixes the buffy coat fraction and hypotonic solution), as well as a filtered buffy coat fraction in elements (ii) and (iii).

Claims 12 and 15-19 also stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement. Specifically, the Office Action argues that without reciting a "static mixer", the claims are not supported by the specification. As discussed above claim 12 is amended herein to recite a static mixture for use in mixing the filtered buffy coat fraction and aqueous hypotonic solution.

In light of these remarks and amendments to the claims, Applicants request that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

**CONCLUSION**

Based on the foregoing, this application is believed to be in condition for allowance. A Notice to that effect is respectfully solicited. However, if any issues remain outstanding after consideration of this Amendment and Reply, the Examiner is respectfully requested to contact the undersigned so that prosecution may be expedited.

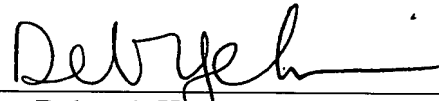
In the event any further fees are due to maintain pendency of this application, the Examiner is authorized to charge such fees to Deposit Account No. 02-4800.

Respectfully submitted,

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Date: December 9, 2003

By: \_\_\_\_\_



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